



PATENT
Attorney Docket No. 3495.0004-04
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Luc MONTAGNIER et al.) Group Art Unit: 1648
Serial No.: 08/067,148) Examiner: J. PARKIN
Filed: May 26, 1993)

For: ANTIBODIES WHICH BIND WITH PROTEINS OF HUMAN IMMUNODEFICIENCY
VIRUS TYPE 1 (HIV-1), AND IMMUNE COMPLEXES COMPRISING PROTEINS
OF HIV-1 (As Amended)

Commissioner for Patents
Washington, D.C. 20231

Sir:

DECLARATION UNDER 37 C.F.R. § 1.132

I, Dr. Jacques H. M. Cohen, do hereby declare as follows:

1. I am a Medical Doctor with a degree from Lyon University.
2. I am currently a Professor at Reims University where I am the Head of the Immunology Department.
3. I am currently manager of an Immunology Laboratory studying immune responses to HIV-1 and hepatitis viruses.
4. I have research experience in anti-viral immune responses. I also have experience in the generation and use of antibodies including monoclonal antibodies. On information and belief, a copy of my CV is attached as Exhibit 1.

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5. On information and belief, U.S. Patent Application No. Ser. No. 08/067,148 filed May 26, 1993, is based on U.S. Patent Application No. Ser. No. 07/832,871 filed February 10, 1992, which is based on U.S. Patent Application No. Ser. No. 07/158,073 filed February 12, 1988, which is based on U.S. Patent Application No. Ser. No. 06/914,156 filed October 1, 1986, which is based on U.S. Patent Application No. Ser. No. 06/706,562 filed February 28, 1985, which is based on U.S. Patent Application No. Ser. No. 06/558,109 filed December 5, 1983. On information and belief, U.S. Patent Application No. Ser. No. 08/067,148 is also based on U.K. 83/24800 filed September 15, 1983, and S.A. 84/7005 filed September 16, 1984. U.S. Patent Application No. 08/067,148 is hereinafter referred to as "the '148 application."

6. On information and belief, a copy of the specification and figures of the '148 application is attached as Exhibit 2.

7. On information and belief, a copy of the pending claims, including claims 45-49, in the '148 application is attached as Exhibit 3.

8. I am informed that claims 45-49 in the '148 application relate to antibodies directed against HIV-1 antigens p12 and p18.

9. On information and belief, the claims of the '148 application were rejected by the Examiner in the U.S. Patent and Trademark Office. I am informed that claims 37-44 were rejected because the specification of the '148 application allegedly does not provide an adequate written description of the invention as it is now claimed.

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10. On information and belief, September 15, 1983, is the earliest date to which a claim for priority has been made in the '148 application.
11. Prior to September 15, 1983, I was familiar with the techniques of isolating viruses, purifying proteins from viruses, and preparing antibodies against viral proteins for the detection of viral proteins.
12. Having read the specification of the '148 application, particularly pages 12-14, I would have understood that the inventors purified HIV-1 p12 and p18 proteins by size using gel electrophoresis.
13. Having read the specification of the '148 application, particularly pages 14-15, bridging paragraph, I would have understood that the HIV-1 p12 and p18 proteins could be purified by many protein purification procedures, such as those disclosed by Montelaro et al., *J. Virology* 42:1029-1038 (1982).
14. On information and belief, a copy of Montelaro et al. is attached as Exhibit 4.
15. Montelaro et al. discloses the isolation of four virion proteins from equine infectious anemia virus using gel filtration techniques. (Montelaro et al. at 1030.) These proteins were used for the production of antiserum against each viral protein in rabbits. (Montelaro et al. at 1035.)
16. The description in the '148 application of how to prepare purified HIV-1 p12 and p18 proteins is sufficiently specific such that I could have followed the description to generate purified HIV-1 p12 and p18 proteins at the time the application was filed.

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17. Having read page 4, lines 1-10, of the specification, I would have understood that the inventors contemplated using purified HIV-1 proteins as immunogens for the production of antibodies in animals against these proteins.

18. Based on the inventors' description of purified HIV-1 p12 and p18 proteins and methods for purifying these proteins, I would have understood that the inventors contemplated using these specific HIV-1 proteins and extracts containing these proteins as immunogens for the production of antibodies in animals.

19. Having read the specification of the '148 application, the generation of antibodies against purified HIV-1 p12 and p18 proteins would have required only techniques that were routine in the art prior to September 15, 1983. For example, the routine techniques discussed in Montelaro et al. could have been used to generate antibodies against all of these proteins in animals.

20. Having read the specification of the '148 application, particularly page 15, lines 17-25, I would have had no reason to believe that the production of antibodies using HIV-1 p12 and p18 proteins as immunogens would not work.

21. The description in the '148 application of how to prepare purified HIV-1 proteins and that these proteins can be used as immunogens for the production of antibodies against HIV-1 proteins is sufficiently specific such that I could have followed the description to generate antibodies against purified HIV-1 p12 and p18 proteins at the time the application was filed.

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22. Based on my ability to follow the description in the '148 application to obtain antibodies against HIV-1 p12 and p18 proteins, I would have concluded that the inventors invented antibodies against these proteins at the time the application was filed.

23. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 1/15/03

By:


Dr. Jacques H. M. Cohen